

Applicants: Albert C. Pierce et al.
Application No.: 10/790,507

REMARKS

Claims 1-39 and 42-46 are pending in the application. Claims 45 and 46 are new. Claims 40 and 41 have been canceled without prejudice as being drawn to a non-elected invention. Claims 1, 39, and 42-44 have been amended. Support for the new claims and claim amendments can be found throughout the application as originally filed, including the claims. Importantly, no new matter has been added. Applicants reserve the right to pursue the canceled subject matter in a continuing application under 35 U.S.C. § 120 or 121.

Rejections Under 35 U.S.C. § 101

Claims 1-39 and 42-44 stand rejected under 35 U.S.C. § 101 based on the Examiner's contention that they are directed to non-statutory subject matter. Applicants respectfully disagree with this rejection.

The Examiner cited the Office's guidance to examiners under the Memorandum "Clarification of 'processes' under 35 USC § 101" (published May 15, 2008), and the "Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility" (November 22, 2005) to support the rejection. Applicants submit that the Examiner's rejection is not in line with current law as promulgated by *In re Bilski*, 545 F.3d 943 (Fed. Cir. 2008), which was decided after these guidelines.

For example, the Examiner on page 4 of the office action dated November 3, 2008, cites paragraph 3 of the above mentioned Memorandum, which states in part "that a § 101 process must (1) be tied to another statutory class (such as a particular apparatus) or (2) transform underlying subject matter (such as an article or materials) to a different state or thing," and then states "[f]urthermore, in the instant invention, there is no *physical* transformation because a process of manipulating structural data of compounds does not transform an *article* or physical object to a different state or thing," (emphasis added).

Applicants submit that the Examiner incorrectly required a *physical* transformation and limited the meaning of *article*. *In re Bilski* addressed these points: "[b]ut the main aspect of the

Applicants: Albert C. Pierce et al.
Application No.: 10/790,507

transformation test that requires clarification here is what sorts of things constitute ‘articles’ such that their transformation is sufficient to impart patent-eligibility under § 101.” *Bilski*, 545 3d. at 962. *In re Bilski* clarified that “articles” includes electronic data:

“We further note for clarity that the electronic transformation of the data itself into a visual depiction in *Abele* was sufficient; the claim was not required to involve any transformation of the underlying physical object that the data represented.”

Bilski, 545 3d. at 963.

Bilski distinguished between a patent-ineligible claim and a patent-eligible claim in *In re Abele*, 684 F.2d 902 (CCPA 1982) which is illustrative of the present application. *In re Abele* involved claims reciting a process of graphically displaying variances of data from average values:

“There, we held unpatentable a broad independent claim reciting a process of graphically displaying variances of data from average values. *Abele*, 684 F.2d at 909. That claim did not specify any particular type or nature of data; nor did it specify how or from where the data was obtained or what the data represented. *Id.*; see also *In re Meyer*, 688 F.2d 789, 792-93 (CCPA 1982) (process claim involving undefined ‘complex system’ and indeterminant ‘factors’ drawn from unspecified ‘testing’ not patent-eligible). In contrast, we held one of *Abele*’s dependent claims to be drawn to patent-eligible subject matter where it specified that ‘said data is X-ray attenuation data produced in a two dimensional field by a computed tomography scanner.’ *Abele*, 684 F.2d at 908-09. This data clearly represented physical and tangible object, namely the structure of bones, organs, and other body tissues. Thus, the transformation of that raw data into a particular visual depiction of a physical object on a display was sufficient to render that more narrowly-claimed process patent-eligible.”

Bilski, 545 3d. at 962-963.

As in *Abele*, where claims specifying the source of the data were patent-eligible, present claims 1, 39, and 42-44, as amended, specify the source of the structural data as either from physical observation or computational inference. Support for the claim amendments can be found on page 6 of specification, lines 3-6. New claims 45 and 46 further specify the source of the structural information as by X-ray, NMR, or

Applicants: Albert C. Pierce et al.
Application No.: 10/790,507

computational means. As in *Abele*, where data represented physical and tangible objects, structural data used here to provide the models represent spatial arrangements of atoms in potential ligands and macromolecular targets.

The Examiner also relied on a patentability analysis using the useful, concrete and tangible result test. However, the useful, concrete and tangible result test is not a proper test for patent-eligible subject matter. *In re Bilski* again states:

“But while looking for ‘a useful, concrete and tangible result’ may in many instances provide useful indications of whether a claim is drawn to a fundamental principle or a practical application of such a principle, that inquiry is insufficient to determine whether a claim is patent-eligible under § 101. And it was certainly never intended to supplant the Supreme Court’s test. Therefore, we also conclude that the ‘useful, concrete and tangible result’ inquiry is inadequate and reaffirm that the machine-or-transformation test outlined by the Supreme Court is the proper test to apply.”

Bilski, 545 3d. at 959-960.

Because the Examiner incorrectly required a physical transformation for the Supreme Court’s transformation test, and for thinking that a transformed article does not include electronic data, and for using the improper useful, concrete, and tangible result test to reject the claims, Applicants submit that the Examiner wrongly rejected claims 1-39 and 42-44 under 35 U.S.C. § 101. Also, in accordance with *In re Bilski*, the present claims have been amended to specify the source of structural information, further qualifying them as patent-eligible. Accordingly, Applicants request the withdrawal of the rejection of claims 1-39 and 42-44 under 35 U.S.C. § 101.

Rejections Under 35 U.S.C. § 112, Second Paragraph

Claims 1-39 and 42-44 stand rejected under 35 U.S.C. § 112, second paragraph, based on the Examiner’s contention that they fail to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. In particular, the Examiner contends that the term “homologous” is a relative term that renders the claims indefinite. Applicants respectfully disagree with this rejection.

Applicants: Albert C. Pierce et al.
Application No.: 10/790,507

Applicants point out that independent claim 44 does not contain the term homologous. Accordingly, Applicants request the withdrawal of the rejection of claim 44 under 35 U.S.C. § 112, second paragraph.

Regarding claims 1-39, 42, and 43, the Examiner states on page 9 of the office action dated November 3, 2008, that “[t]he term is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.” Applicants disagree with this assertion and submit that one of ordinary skill in the art would understand what is claimed when the claim is read in light of the specification.

“Homologous” as used in the claims describes structural features (see claims 1, 39, 42, and 43). Guidance for structural homology is given throughout the specification. For example, on page 2, lines 20-26, of the specification, homology of the target molecule can be, for example, a peptide backbone, which one of ordinary skill in the art would recognize exists in proteins of the same family. Homology of the ligand is described as the framework or pharmacophore of the ligand, which one of ordinary skill in the art would know refers to the spatial arrangement of the functional groups of the ligands. These guidelines apply to the three-dimensional structural information used in step (1) of the independent claims.

When the target molecule is a protein, homologous is standardized in terms of amino acid homology on page 3, lines 18-20, of the specification. Amino acid homology may be 25%, 40%, or greater, such as, for example, a shared polypeptide fold.

Page 6, lines 8-10, reiterate that homology between the ligands is based on the framework of the ligands, or between pharmacophore models of the ligands.

Page 11, lines 14-27, refer to the flow diagram of Figure 1, and describe how one of ordinary skill in the art can specify a homologous structural feature which must be shared between the ligands and/or target molecule. An example is then given between an enzyme and two inhibitor ligands.

Applicants remind Examiner that “[t]he failure to define a term is, of course, not fatal, for if the meaning of the term is fairly inferable from the patent, an express definition is not

Applicants: Albert C. Pierce et al.
Application No.: 10/790,507

necessary...” *Bancorp Services v. Hartford life Insurance Co.*, 359 F.3d 1367 (Fed. Cir. 2004). From M.P.E.P. § 2173.01 “[a] fundamental principle contained in 35 U.S.C. 112, second paragraph is that applicants are their own lexicographers,” and from M.P.E.P. § 2173.02 “[s]ome latitude in the manner of expression and the aptness of terms should be permitted even though the claim language is not as precise as the examiner might desire.”

Applicants submit that in light of the description of homologous found in the specification as described above, and the latitude they are entitled to as their own lexicographer, the claims apprise one of ordinary skill in the art of their scope, and, therefore, serve the notice function required by 35 U.S.C. § 112, second paragraph.

Accordingly, Applicants request the withdrawal of the rejection of claims 1-39 and 42-44 under 35 U.S.C. § 112, second paragraph.

Applicants: Albert C. Pierce et al.
Application No.: 10/790,507

Fees

The Director is hereby authorized to charge any additional fee due, or credit any overpayment, in connection with this petition, to Deposit Account No. 50-0725.

Conclusion

Applicants request that the Examiner enter the above election, and allow the pending claims to pass to issue. If a call to Applicants' representative would help to expedite the prosecution of this application, the Examiner is encouraged to contact the undersigned.

Respectfully submitted,

/Michael J. DiVerdi/
Michael J. DiVerdi, Ph.D. (Reg. No. 51,620)
Attorney for Applicants
c/o Vertex Pharmaceuticals Incorporated
130 Waverly Street
Cambridge, MA 02139-4242
Tel.: (617) 444-7503
Fax.: (617) 444-6483